No. 83-196

IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR,
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Appellant,

v.

MONSANTO COMPANY,
Appellee.

On Appeal From The United States District Court For The Eastern District Of Missouri

BRIEF OF SDS BIOTECH CORPORATION, ATLANTIC & PACIFIC RESEARCH, INC., AND PBI-GORDON CORPORATION AS *AMICI CURIAE* IN SUPPORT OF APPELLEE

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This brief is filed on behalf of SDS Biotech Corporation ("SDS"), Atlantic & Pacific Research, Inc. ("A&P"), and PBI-Gordon Corporation ("PBI") with the parties' consent.

INTEREST OF *AMICI CURIAE*

SDS, A&P, and PBI are, to varying degrees, engaged in the invention, manufacture, formulation, and distribution of pesticides. All three are therefore subject to the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (1982) ("FIFRA"), including the mandatory data licensing provisions of Section 3(c)(1)(D), 7 U.S.C. § 136a(c)(1)(D). The operation of these statutory provisions has been fully

described by the parties. Like Monsanto Company, in whose support *amici* file this brief, *amici* have a substantial interest in affirmance of the ruling below that FIFRA's mandatory licensing provisions are unconstitutional.

SDS is a Delaware corporation, formed in 1983,[1] that invents, manufactures, and distributes pesticides. SDS depends on the fungicide chlorothalonil, which it invented, for over half of its sales and profits. SDS has spent millions of dollars over the last two decades to generate the data necessary to obtain its chlorothalonil registrations and maintain them in effect. If the decision below is not affirmed, SDS will lose its valuable property rights in these trade secret data.

Indeed, given the potential harm to SDS from the mandatory licensing provisions, SDS in 1979 prepared its own complaint challenging the constitutionality of those provisions. In view of SDS's complaint and the pendency of Monsanto's and similar cases, EPA agreed in June, 1979, in consideration of SDS's forbearance from seeking immediate injunctive relief, not to register pesticides containing chlorothalonil without thirty days' advance notice to allow SDS to protect its interests. However, under the challenged provisions, a follow-on registrant, Griffin Corporation ("Griffin"), obtained a chlorothalonil registration on the basis of SDS's data, without SDS's consent, without the notice required by the 1979 agreement, and to SDS's substantial detriment. EPA has initiated an administrative proceeding to consider cancelling that registration in light of the Agency's admitted breach of its agreement.[2]

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[1] Prior to SDS's formation, the pesticides now registered by SDS were registered by Diamond Shamrock Corporation. In July, 1983, SDS acquired all of Diamond's rights and interests in chlorothalonil, *see infra*, and certain other pesticides. Accordingly, this brief will use "SDS" to refer both to Diamond, with respect to events prior to formation of SDS, and to SDS with respect to events thereafter.

[2] Notice of Intent to Hold a Hearing, 49 Fed. Reg. 508 (1984).

A&P is a small Florida corporation with yearly sales of $750,000 to $1 million. In terms of the pesticide industry it is extremely small and holds only one registration, for CYTEX, a plant growth regulator. A&P obtained its registration on the basis of its own data after several years of research. Within two years the data had been used, without A&P's consent, to approve registrations for at least two other companies. This unconsented use of A&P's data has damaged A&P's ability to obtain a return on its investment. Moreover, A&P believes that the follow-on registrations were for products that are not identical to A&P's. Without complete data on the specific products registered, it is doubtful whether EPA can assure the public that the follow-on products do not pose unreasonable risks to health and the environment. Although A&P has developed ideas for other new pesticides, FIFRA's failure to protect proprietary rights significantly impairs A&P's willingness and ability to engage in the risky, time-consuming, and costly process of developing new pesticides.

PBI is a Missouri corporation engaged in the formulation, distribution, and sale of pesticides. PBI is a member of the Pesticide Producers Association ("PPA"), but its interests lead it to file this brief on behalf of Monsanto and not, like PPA, in support of EPA.[3] Although PBI does not engage in research to discover new pesticides, it always obtains a developer's consent before relying on the developer's data to support a registration application. In addition, PBI does conduct research intended to discover new uses for existing pesticides. New uses, like new pesticides, must be registered and supported by extensive research and test data, which are then available to follow-on registrants through mandatory licensing. Through its efforts, PBI acquires valuable information known only to it, which affords it a significant competitive advantage. The development of new uses for existing prod-

[3] Brief of the Pesticide Producers Association, Drexel Chemical Company, Falls Chemicals, Inc., and Griffin Corporation as *Amici Curiae* ("PPA Br.").

ucts, like new products, benefits American agriculture and the consumer. A company's willingness to conduct this research and development depends not upon whether it is large or small—PBI is small with yearly sales of less than thirty million dollars—but upon whether it can earn an adequate return on its investment. Doing so is particularly difficult with respect to research on products already in the marketplace. On such products with no patent protection, trade secret protections afford the only competitive advantage for the innovating company. Only if this Court protects the proprietary rights acquired by the significant investment of time, effort, and money in the development of trade secret data can companies engaged in research and development obtain a return justifying the substantial risks involved.

Accordingly, *amici* file this brief to protect their property rights in their pesticide registration data, to respond to erroneous assertions in the PPA Brief, to which Griffin is a party, and to urge the Court not to accept the implicit invitation of other *amici* to foreclose retroactive application of an affirmance.

SUMMARY OF ARGUMENT

SDS, A&P, and PBI seek to bring to this Court a fundamentally different perspective from that offered by EPA and its supporting *amici* on how the issues in this case must be weighed. From reading the briefs of Appellant and its supporters, one would conclude that FIFRA is a statute intended primarily to regulate competition and only incidentally to protect public health and safety through the regulation of pesticides. To the contrary, as the legislative history of the statute overwhelmingly demonstrates, Congress' primary goal in FIFRA has been the development of a system of regulating and monitoring pesticides that will fully protect health and the environment. The very few provisions of the law that address competitive issues create a benefit solely for a handful of private companies, impair EPA's ability to protect health and safety, and serve no public purpose. It is in this context that the Court must scrutinize the challenged provisions of FIFRA.

I. Of the several thousand firms that sell pesticides, only forty or so, both large and small, attempt to develop and manufacture new pesticides and generate the data necessary for their registration. These efforts typically require an extraordinary investment of time and money, and a willingness to undertake substantial risks of failure.

Most of the roughly 3,300 firms that sell finished pesticide products rely on a FIFRA provision that obligates them to purchase the basic pesticidal chemicals from manufacturers in order to formulate end-use products, rather than manufacture those active ingredients themselves. Sales of registered active ingredients to such "formulators" occur only after arm's-length negotiations and a completed compensation arrangement. These arrangements enable manufacturers to recover some of the costs of developing the chemicals. The formulators need not submit or cite data on the purchased active ingredients, although they may be required to submit or cite certain additional data to register their end-use products.

There remains only a narrow third class of firms—roughly ninety manufacturers that obtain follow-on registrations and avoid virtually all data submission requirements—about which this case is concerned. Relying on the mandatory licensing provisions, they receive all the benefits of new pesticide development and data generation without having to conduct such research themselves or to enter into voluntary, arm's-length negotiations with developers. Compensation for the developers, if any, may not occur until years after a follow-on registrant has entered the market, and does not justly compensate the developer. It is these follow-on firms to which mandatory licensing directs a major private benefit, at the expense of the original pesticide manufacturers and data developers and the formulators that share in development costs through their purchases of active ingredients. No substantial public benefit is produced by thus favoring this small group, since pesticide prices already are limited by other factors, including competition among different types of products.

II. The FIFRA mandatory licensing scheme permitting use of *amici's* trade secret data is clearly a taking of their property. It destroys the essential benefit conferred by ownership of a trade secret, *i.e.*, the competitive advantage that results from the ownership and development of such data.

That taking is unconstitutional because it is for private purposes. Judicial analysis of whether the taking is for private or public purposes cannot rest solely on Congress' statements of its purposes because those statements are inconsistent: the allegedly "public" purposes of mandatory licensing undermine FIFRA's primary objective of protecting health and the environment. Accordingly, the Court must look to the actual operation of the statute to determine its purpose and effect. Scrutiny of the challenged provisions reveals that they benefit only a small class of private parties for whom the prerequisites to the sale of pesticides—prerequisites created by Congress to protect health and the environment—are waived. This benefit deprives EPA of health and safety data that otherwise would be available, and confers little or no public benefit in the form of increased competition. In short, mandatory licensing is the reverse of a constitutional taking, in which there is a public purpose with incidental private benefit. Here there is a private purpose with only incidental, if any, public benefit.

Even if this Court were to find a public purpose, the taking nevertheless would be unconstitutional, because just compensation for data developers is unavailable.

III. *Amici* in support of Appellant have referred to the possible effect of an affirmance on previously issued pesticide registrations. Such references implicitly invite the Court to address the question of retroactive application of its ruling. The Court need not reach that question to decide this case and should not consider the issue of retroactivity in the absence of a factual record on which to base its review. The general rule, which favors retroactivity unless a decision clearly breaks with prior law relied on by litigants and unless retroactivity would

retard the purposes of the new decision or create inequities, clearly requires a factual inquiry into the circumstances of a case in which retroactive application is sought. Such an inquiry may find retroactivity to be more appropriate in some cases than others. The Court therefore should not attempt to anticipate the different circumstances in which the issue could arise, and should not foreclose retroactive relief in an appropriate case with a record on that issue.

ARGUMENT

I. FIFRA'S MANDATORY DATA LICENSING PROVISIONS TRANSFER A MAJOR ECONOMIC BENEFIT TO A NARROW CLASS OF FOLLOW-ON REGISTRANTS WITHOUT SIGNIFICANTLY PROMOTING COMPETITION.

FIFRA is unique among federal health and safety statutes in the favor it gives to one small segment of the regulated community. Mandatory data licensing grants a major unearned economic benefit to a few follow-on registrants, at the expense of those that develop, evaluate, and submit safety data and those that properly compensate the data submitters.

A. The Pesticide Industry Consists Of Three Classes Of Companies, Two Of Which Play A Major Direct Or Indirect Role In The Development Of Research And Test Data.

A recent EPA study found that approximately 130 firms in the United States produce basic pesticide chemicals.[4] These producers, some as small as A&P, manufacture approximately 1,000 different active ingredients, each registered with EPA.[5]

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[4] U.S. Environmental Protection Agency, Regulatory Impact Analysis: Data Requirements for Registering Pesticides Under the Federal Insecticide, Fungicide, and Rodenticide Act 81, 82, 86 (1982) ("Regulatory Impact Analysis").

[5] *Id.* at 81. Approximately 35,000 different finished products have been registered. *Id.*

These chemicals normally must be dissolved, diluted, or otherwise formulated into finished products.[6] Approximately 3,300 firms are engaged in such formulation, including many that also manufacture the basic pesticide chemicals.[7]

Roughly forty of the 130 producers are responsible for the research and development that both identifies potential new pesticides and tests them for safety and efficacy.[8] Whether large or small, the firms that develop and register a new pesticide, referred to here as "developers," are also those that generate the data necessary to demonstrate safety.

The remaining firms that produce or formulate pesticides rely for their entry into the market on the work done by the developers. These firms can be divided into two groups: those registering products in reliance on the "formulator's exemption," and those registering products by citing data submitted by previous registrants. The great majority rely upon Section 3(c)(2)(D) of FIFRA, the formulator's exemption.[9] To qualify for that exemption, the formulator may not manufacture the active ingredient but must purchase a registered pesticide from its developer or another producer for formulation into an end-use product, and is then exempt from citing the data

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[6] S. Rep. No. 334, 95th Cong., 1st Sess. 37 (1977).

[7] Regulatory Impact Analysis 130-31 (1982). A Senate committee in 1977 found that there were about 400 producers of basic pesticide chemicals and about 5,300 plants engaged in pesticide formulation. S. Rep. No. 334, 95th Cong., 1st Sess. 27-28 (1977). These numbers are larger than those in the EPA study, presumably because the committee report counted plants and the EPA study counted firms.

[8] S. Rep. No. 334, 95th Cong., 1st Sess. 27 (1977). A recent industry survey found 36 companies reporting some research and development activity, which suggests that the above estimate is still roughly accurate. National Agricultural Chemicals Association, 1982 Industry Profile Study 2-3 (1983).

[9] *See* Regulatory Impact Analysis 130-31 (1982).

supporting the registration of the purchased product and from offering to compensate the developer.[10] The formulator's exemption in effect allows a developer, after arm's-length negotiations and at the outset, to sell to formulators at a price sufficient to recoup its development and registration costs.[11] Indeed, the rationale for the exemption was that a formulator purchasing a registered pesticide already pays some amount, included in the agreed-upon purchase price, that reflects the developer's cost of generating the registration data for that chemical.[12] Registrations issued pursuant to the formulator's exemption, unlike registrations issued under the provisions challenged here, thus benefit developers as well as the subsequent registrants and are not at issue in this case.

The ninety or so remaining registrants,[13] which are neither developers nor among the vast majority that rely on the formulator's exemption, are the small class of registrants about which this case actually is concerned. These follow-on registrants register products by relying on data submitted by prior registrants. Only this handful of companies obtains all of the economic benefits of registration without generating the necessary data or properly compensating those who do. The data compensation provisions of FIFRA do not assure developers of adequate cost recovery. Unlike the up-front,

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[10] FIFRA § 3(c)(2)(D), 7 U.S.C. § 136a(c)(2)(D). The formulator may be required to submit or cite health and safety studies on its particular end-use formulation. 40 C.F.R. § 162.9-8(a) and (b) (1983).

[11] *See* Regulatory Impact Analysis 131 (1982).

[12] *See, e.g.*, 123 Cong. Rec. 36000 (1977) (remarks of Rep. Foley); *Extending and Amending FIFRA: Hearings Before the Subcomm. on Department Investigations, Oversight and Research of the House of Representatives Comm. on Agriculture*, 95th Cong., 1st Sess. 173 (1977).

[13] This number is based primarily on the difference between the total number of producers (approximately 130; *see* n.4, *supra*) and the number of producers who develop new pesticides (approximately 40; *see* n.8, *supra*).

voluntary, arm's-length negotiations between a developer and a formulator, a developer receiving an inadequate compensation offer from a follow-on registrant will ultimately be bound by arbitration ending years after the follow-on company is on the market. There have been only three compensation decisions under FIFRA to date, and they have awarded developers only a small fraction of the cost, and a smaller fraction of the value, of their data. *See* pp. 25-26, *infra*.

Moreover, because these follow-on registrants are not involved in generating the required safety data, they often know little about the health effects of the products they sell. *See, e.g.*, Brief for the AFL-CIO *et al.* as *Amici Curiae* in Support of Appellant ("AFL-CIO Br.") 27-28 n.18; Brief of the American Chemical Society *et al.* as *Amici Curiae* in Support of Appellee ("ACS Br.") 13-14. Affirmance of the decision below therefore would advance health and safety protection by ensuring that pesticides enter the marketplace through companies that test and remain attentive to the effects of their products or through parties to commercial relationships with the developers, which have the major investment incentive to ensure that their purchasers properly formulate and label the products sold. *See, e.g.*, ACS Br. at 13-14.

B. Firms That Develop And Register New Pesticides Do So At Great Expense And Economic Risk.

For those firms, large and small, that accept the risk and expense of developing and registering new pesticides and new uses for existing pesticides, the cost has always been substantial, and is rising. Innovation requires synthesis of new compounds, screening for biological and pesticidal activity, and a gauntlet of increasingly demanding tests for safety and efficacy, including those required to support registration.[14] The direct costs of meeting registration requirements have

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[14] J.S. App. 5a-7a. *See also* National Agricultural Chemicals Association, 1982 Industry Profile Study 9 (1983).

been estimated by EPA at 1.8 to 2.8 million dollars per major crop chemical, and, by a Senate committee some years ago, at seven million dollars for a food use pesticide.[15] These estimates may be low; SDS's costs of developing its chlorothalonil registration data, for instance, are many times EPA's estimates. Even after registration, EPA often requires additional data; SDS has been generating the test data to obtain and maintain its chlorothalonil registrations from the mid-1960's until the present, and A&P has continued to generate data on CYTEX. In addition, the development by PBI and others of new uses for a product requires substantial additional research on the product's effectiveness for the new uses and the generation of data to support registration of those uses.

Furthermore, the costs described above are only a small portion of the total research and development costs necessary to develop a new pesticide. Over 10,000 compounds are synthesized for each one that succeeds,[16] and the number of compounds that must be screened to yield a viable product is increasing.[17] Taking into account the costs of screening compounds rejected at some stage in the process, EPA has estimated the cost of bringing a new chemical to market to be between twenty and seventy million dollars.[18] Although all

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[15] Regulatory Impact Analysis 89 (1982); S. Rep. No. 334, 95th Cong., 1st Sess. 30 (1977).

[16] *See, e.g.*, Regulatory Impact Analysis 129 (1982) (89,343 compounds screened and seven conditional registrations granted for new products in 1980).

[17] ICF, Inc., Economic Profile of the Pesticide Industry 57 (1980).

[18] Regulatory Impact Analysis 90 (1982). The latest industry data support this estimate. In 1982, thirteen new pesticide products were registered, while the industry spent over $346 million for new pesticide research, out of a total research and development effort of over $526 million. National Agricultural Chemicals Association, 1982 Industry Profile Study 7, 9 (1983). Thus, over $26 million was spent per new product registration.

these costs must be absorbed by sales of the few successful chemicals,[19] only a minute portion have been considered compensable pursuant to the data compensation provisions of FIFRA.[20]

The mandatory data licensing provisions do not work a transfer merely from large to small firms. Contrary to suggestions that mandatory licensing is necessary to permit small firms to participate in the industry,[21] small firms play a significant role in developing new products and uses. A&P and PBI are both small companies engaged in such work, and two of the seven registrations granted for new pesticides in 1980 were to small producers, with annual sales under fifteen million dollars.[22] Therefore, small as well as large firms are substantially injured by mandatory licensing.

C. Mandatory Licensing Transfers A Major Unearned Benefit To A Small Class Of Follow-On Registrants.

Issuance of a follow-on registration can have a major economic impact upon both the developer and the follow-on registrant. Because the follow-on registrant, unlike the developer, has not spent millions of dollars on the safety and efficacy data necessary to obtain the original registration, nor the tens of millions of dollars necessary to evaluate thousands of other compounds ultimately rejected, the follow-on registrant has a significant artificial cost advantage that may be translated into substantial windfall profits.

Thus, the mandatory licensing process transfers a major economic benefit directly from the developer to the follow-on registrant. The resulting economic injury is particularly pronounced for those developers, large and small, that depend

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[19] S. Rep. No. 334, 95th Cong., 1st Sess. 36 (1977).

[20] *See* pp. 25-26, *infra*.

[21] *See* PPA Br. at 3-4, 15-16.

[22] Regulatory Impact Analysis 128-29 (1982).

primarily on sales of one or two pesticide chemicals they have developed.[23] A&P and SDS are such companies: CYTEX is A&P's only product, and chlorothalonil products account for over half of SDS's sales and profits.

In sum, mandatory licensing takes the value of test data away from innovators in the pesticide field by using the data for the private benefit of a small class of follow-on registrants.

D. Mandatory Data Licensing Is Not Necessary To Ensure Competitive Pesticide Prices.

Even in the absence of the mandatory licensing provisions, the developer of a new pesticide would be limited in the price it could charge, contrary to assertions that only those provisions prevent developers from raising their prices "with impunity." PPA Br. at 16. Competition from alternative pesticides already tends to lower prices, reducing the likelihood of a "sharp price drop" as a result of another company's marketing of the same product.[24] A study done for EPA found an average of five competing herbicides and five different insecticides available for use on each of the major crops reviewed.[25]

Even for the few pesticide needs that are satisfied primarily by one or a few products, the constant process of innovation leads to the replacement of dominant products and firms by new ones.[26] The source of such new competing products, of

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[23] *See Extension of the Federal Insecticide, Fungicide, and Rodenticide Act: Hearings Before the Subcomm. on Agricultural Research and General Legislation of the Senate Comm. on Agriculture, Nutrition, and Forestry*, 95th Cong., 1st Sess. 251 (1977).

[24] EPA, Agricultural Impact Analysis of Chlorothalonil 7 (1983) ("Agricultural Impact Analysis").

[25] ICF, Inc., Economic Profile of the Pesticide Industry, 16-20 and Exs. 1-26—1-35 (1980).

[26] *Id.* at 17, 22. As EPA has found, new product discovery is one of the major routes by which competitive advantage is sought in the pesticide industry. Regulatory Impact Analysis 84 (1982).

course, is not the follow-on registrants but the companies that take the risks to invest in the development of new products—risks that companies are encouraged to take if the value of their trade secrets is protected.

The chlorothalonil example adds concrete evidence that mandatory data licensing is not necessary to ensure competitive pesticide prices. The EPA study cited in the PPA Brief at 12-13 evaluated the economic impact of cancellation of Griffin's follow-on registration, which would leave SDS as the only registrant of technical chlorothalonil. The study found that even the "worst case" possibility, a five dollar per gallon price rise, would have no significant impact on crop or food prices, largely because pesticide costs are such a small proportion of the total cost of crop production.[27] Moreover, EPA has recognized that such a pricing decision is the result of numerous business considerations, such as the desire to penetrate new markets by lowering prices, and does not depend solely on the presence or absence of competitors selling identical products.[28]

Even if the presence of different companies selling the same product is a positive influence on pricing, elimination of mandatory licensing would not destroy that influence. The argument that almost every small company would be forced off the market if the decision below is affirmed, PPA Br. at 4, is simply wrong. Those companies could generate their own data as do other registrants, including those as small as A&P. They could also rely on the formulator's exemption, as do most small companies, or they could, like PBI, obtain developers' permission to rely on previously submitted data through arm's-length

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[27] Agricultural Impact Analysis 1, 9-11 (1983); Notice of Intent to Hold a Hearing, 49 Fed. Reg. 509 (1984).

[28] *See* Agricultural Impact Analysis 7-9 (1983); Notice of Intent to Hold a Hearing, 49 Fed. Reg. 510-11 (1984).

negotiations.[29] This is how EPA's pesticide registration program currently is operating in response to the district court's decision. *See* EPA P.R. Notice 83-4 as amended by P.R. Notice 83-4A (1983).

It is also how the new drug application procedures of the Food and Drug Administration ("FDA") have operated for years. In fact, the absence of a significant competitive benefit from mandatory licensing is illustrated by the preservation of competition in the pharmaceutical industry without resort to a statutory giveaway for the benefit of follow-on registrants. FDA requires applicants for approval of follow-on drugs to meet the same data requirements imposed upon manufacturers of "pioneer drugs." 21 U.S.C. § 355 (1982); 21 C.F.R. § 314.1 (1983); *United States* v. *Generix Drug Corp.*, ___ U.S. ___, 103 S. Ct. 1298 (1983). Neither the statute nor the regulations allow follow-on applicants to use, or FDA to consider, data submitted by the pioneer registrant.[30] As this Court ob-

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[29] Affirmance would not be a *de facto* extension of patent protection. A patent confers exclusive rights to a product for a period of time. Trade secret protection prevents use or disclosure of valuable commercial information but does not prevent another company from developing similar information on its own or from obtaining a pesticide registration to market the product to which that information relates. Patents and trade secrets create separate sets of rights, each entitled to protection. *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974). The protection of one such set of rights has no effect on the other, as is clearly illustrated by EPA's issuance of follow-on registrations for currently patented products. In the case of chlorothalonil, for example, SDS's patents do not expire until July, 1984, yet Griffin has already obtained two registrations in reliance on SDS's data. EPA therefore is simply incorrect in asserting that the "data consideration provisions come into play when the chemical or product is not patentable or when patent protection has expired." Brief for the Appellant ("App. Br.") at 13.

[30] Manufacturers of follow-on drugs duplicating pioneer drugs approved before 1962 may in limited circumstances be permitted to file an abbreviated new drug application and therefore to rely on data

served only last term, the subsequent applicants still enjoy a cost advantage, despite the costs of developing the necessary data on their own. *Id.* at 1299 n.1 (1983).

In short, FIFRA's transfer of a large unearned private benefit to follow-on registrants creates no significant public benefit in terms of increased competition or lower prices for agricultural products.

II. THE MANDATORY DATA LICENSING SCHEME IS AN UNCONSTITUTIONAL TAKING OF DATA SUBMITTERS' PROPERTY FOR PRIVATE PURPOSES AND WITHOUT JUST COMPENSATION.

In light of the purposes of FIFRA and the structure of the pesticide industry set forth above, it is clear that the mandatory licensing scheme is unconstitutional.[31]

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generated by the FDA itself through its Drug Efficacy Study Implementation. 21 C.F.R. § 314.2 (1983). Any manufacturer, including one seeking to copy a post-1962 drug, may demonstrate safety and effectiveness by relying on reports of studies in the published literature. 48 Fed. Reg. 2751, 2753 (1983).

[31] The discussion below focuses on the data licensing rather than disclosure provisions of FIFRA. Although SDS, PBI, and A&P agree that a mechanism for public review of EPA's decisions is appropriate and desirable, *see* AFL-CIO Br.; Brief of the American Association for the Advancement of Science *et al.* as *Amici Curiae* in Support of Appellant ("AAAS Br."), they share Appellee's view that the FIFRA disclosure provisions are unconstitutional. Possible alternatives include increased reliance on the FIFRA Scientific Advisory Panel, disclosure of nonconfidential summaries of data, and the use of reading rooms where persons other than competitors could review registration data. Other constitutional alternatives are available.

A. Data Submitters Have Protected Property Interests In Their Registration Data And The Mandatory Licensing Provisions Effect A Taking Of That Property.

For the reasons set forth by Monsanto, all three *amici* have protected property interests in their data.[22] It is clear that the mandatory licensing scheme "takes" this property. EPA attempts to minimize the invasion of the developers' property interests by arguing that the licensing provisions affect only the competitive advantage conferred by the data and do not prevent other uses of the data. App. Br. at 36, 38; *see also* AFL-CIO Br. at 27. The competitive advantage, however, is the essence of the owner's interest in a trade secret: "A trade secret may consist of any . . . compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." Restatement of Torts § 757, comment b (1939).

The owner's interest in ensuring that his competitors "do not know or use" his trade secret—his "right to exclude"—is precisely the interest destroyed. The argument that the destruction of this interest is permissible because it is only one of a developer's "bundle of rights," App. Br. at 35-36; PPA Br. at 22, is contrary to this Court's holding that a taking of the right to exclude is of constitutional dimension. *Kaiser Aetna* v. *United States*, 444 U.S. at 179-80. That holding should apply

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[22] Ohio, Florida, and Missouri, where SDS, A&P, and PBI are located, all recognize and protect trade secrets as property and have adopted the Restatement of Torts § 757 definition of trade secrets. *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. at 474; Cincinnati Bell Foundry Co. v. Dodds, 10 Ohio Dec. Reprint 154, 154-55 (Super. Ct. 1887); Ohio Rev. Code Ann. § 1333.51 (Page 1979); Lee v. Cercoa, Inc., 433 So.2d 1 (Fla. Dist. Ct. App. 1983); Unistar Corp. v. Child, 415 So.2d 733 (Fla. Dist. Ct. App. 1982); J.S. App. 22a, 29a-31a. This Court often looks to state law as determinative of the existence of a property interest, including in taking cases. *E.g.*, Kaiser Aetna v. United States, 444 U.S. 164, 179 (1979).

with particular force in the case of trade secrets, where the right to exclude is the entire bundle of rights.

The complete destruction of developers' property is illustrated by EPA's comment that a data submitter may avoid the licensing provisions by refraining from seeking registrations. J.S. at 16.[33] Since a registration is necessary to sell any pesticide product, EPA's suggested alternative would render worthless both the data and the other investments made in developing a pesticide for sale. That developers choose to seek registrations rather than to cease inventing, developing, and marketing pesticides does not mean that the unconsented use of the data on behalf of a competitor is not a taking. The developer has no choice that will assure full recovery of its investment. It may choose only between different losses of its investment.

B. The Taking Of Data Developers' Property Is For Private Purposes And Is Therefore Unconstitutional.

Despite its traditional deference to congressional statements of purpose, the Court's resolution of taking cases ultimately depends on "ad hoc, factual inquiries" into the circumstances of each case. *Kaiser Aetna* v. *United States*, 444 U.S. at 175. Such an inquiry into the operation of mandatory licensing leads clearly to the conclusion that the taking it effects is for private purposes and is therefore unconstitutional.

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[33] Similarly, EPA has argued that developers waive their property rights when they submit the data to obtain the benefit of a registration. App. Br. at 27, 30. This argument proves too much. It is well settled that the government may not condition the granting of a benefit on the recipient's surrender of a constitutional right. Such conditions have long since been rejected by this Court as unconstitutional. *See* Lefkowitz v. Turley, 414 U.S. 70 (1973); Spevak v. Klein, 385 U.S. 511 (1967); Garrity v. New Jersey, 385 U.S. 493 (1967); Sherbert v. Verner, 374 U.S. 398 (1963); Speiser v. Randall, 357 U.S. 513, 526 (1958) (government may not act indirectly to "produce a result which [it] could not command directly").

1. A taking for private purposes is unconstitutional.

If a taking is for private purposes, it is unconstitutional. *Thompson* v. *Consolidated Gas Utilities Corp.*, 300 U.S. 55 (1937), invalidated a state administrative order limiting natural gas production. That order forced companies that had built pipelines and developed markets to purchase gas from companies that had not done so, since the production limits would have prevented the pipeline companies from selling enough gas to satisfy their markets. The companies with pipelines and markets had acquired them "at large cost," *id.* at 66, and the owners of other wells had "not contributed in money, services, negotiations, skill, forethought or otherwise to the development of such markets and the construction of such pipelines and other facilities," *id.* at 78. The Court held that "one person's property may not be taken for the benefit of another private person without a justifying public purpose, even though compensation be paid." *Id.* at 80.

Similarly, *Pennsylvania Coal Co.* v. *Mahon*, 260 U.S. 393 (1922), struck down a state statute prohibiting coal mining that would cause the collapse of structures belonging to parties owning only the surface rights to the land. The Court ruled this prohibition a taking of valuable property rights that the coal company had expressly reserved when it conveyed the surface rights. The Court found no "public interest sufficient to warrant so extensive a destruction" of the coal company's property. *Id.* at 414. As for the benefits conferred on other surface right owners who were not parties to the case, the Court did not find them adequate to establish a public purpose, reasoning that the owners had "seen fit to take the risk of acquiring only surface rights, [and] we cannot see that the fact that their risk has become a danger warrants the giving to them greater rights than they bought." *Id.* at 416.

More recently, the Ninth Circuit invalidated the Hawaii Land Reform Act, which permitted certain lessees to acquire the land they leased by means of eminent domain. Despite the state legislature's justification of the act as a means of redressing a shortage of fee simple land and resulting inflation, the

court found the taking to serve private purposes and held it unconstitutional. *Midkiff* v. *Tom*, 702 F.2d 788 (9th Cir.), *prob. juris. noted sub nom. Hawaii Housing Authority* v. *Midkiff*, ___ U.S. ___, 104 S. Ct. 334 (1983).

The hallmark of *Thompson* and *Pennsylvania Coal* is that the parties upon whom the challenged provisions conferred a benefit could have obtained that benefit themselves by investing in pipelines and market development or by purchasing more than the surface rights to the land on which they built. Under such circumstances it is impermissible for the government to transfer these benefits from parties who have made such investments to those who have not seen fit to undertake the same burdens. Yet that is exactly what FIFRA does. Companies that obtain follow-on registrations could make the investment to develop the required data, in which case their right to the benefits of a registration would be unquestioned. To give them the benefit of other companies' investments, however, is to transfer property from one private party to another and is beyond Congress' authority under the Constitution.

2. The private purpose of the challenged provisions is clear from their operation and effect.

The deference traditionally owed to congressional statements of purpose, *e.g.*, *Berman* v. *Parker*, 348 U.S. 26, 32 (1954), does not end the inquiry into the purpose of a challenged statute. The determination of a statute's constitutionality is a judicial one. Congress cannot immunize a statute from judicial scrutiny merely by reciting so-called "public purposes" in the statute or its legislative history. *St. Joseph Stock Yards Co.* v. *United States*, 298 U.S. 38, 50-52 (1936).[34]

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[34] *See also* United States ex rel. TVA v. Welch, 327 U.S. 546, 556-57 (Reed, J., concurring), 557-58 (Frankfurter, J., concurring) (1946); Midkiff v. Tom, 702 F.2d at 798 ("were Congress to . . . allow condemnation of A's private property for transfer to B, solely for B's private use, this court would necessarily find such action contrary to the fifth amendment whether or not Congress declared such proceed-

Moreover, unlike the statute at issue in *Berman* v. *Parker*, FIFRA contains no statement of its purposes. In the absence of such a statement, Appellant relies heavily on legislative history references to certain allegedly public purposes: promotion of competition and avoidance of "duplicative" testing. App. Br. at 12, 21-24. These statements, however, must be viewed in the context of FIFRA as a whole. Since its comprehensive revision in 1972, the statute has been primarily intended to regulate pesticides for the purpose of protecting health and the environment.[35] As discussed below, the limited "public purposes" claimed for mandatory licensing are inconsistent with this broader public purpose. Accordingly, because the legislative history of the statute defies attempts to characterize its purposes in a unified and consistent manner, the actual effect of the statute is the only reliable guide to its purposes. A review of the effect of mandatory licensing demonstrates that it serves private purposes.

Despite the legislative history statements that mandatory licensing was designed to promote competition, FIFRA, unlike most pro-competitive legislation, does not attempt to prohibit unfair methods of competition or to prevent unequal barriers to market entry. On the contrary, the promotion of "competition" referred to in the legislative history is simply the creation of an unfair and unequal opportunity for a narrow group of companies to avoid health and safety requirements thought to be sufficiently important to justify requiring some

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ings to be for a public purpose"); Wearly v. FTC, 462 F. Supp. 589, 603 (D.N.J. 1978), *vacated on other grounds*, 616 F.2d 662 (3d Cir.), *cert. denied*, 449 U.S. 822 (1980).

[35] *See* S. Rep. No. 551, 97th Cong., 2d Sess. 1 (1982); H.R. Rep. No. 566, 97th Cong., 2d Sess. 33 (1982); S. Rep. No. 334, 95th Cong., 1st Sess. 33 (1977); Staff of Subcomm. on Administrative Practice and Procedure of Senate Comm. on the Judiciary, 94th Cong., 2d Sess., *The Environmental Protection Agency and the Regulation of Pesticides* 3 (Comm. Print 1976); S. Rep. No. 838, 92d Cong., 2d Sess. 3 (1972); H.R. Rep. No. 511, 92d Cong., 1st Sess. 1, 4 (1971).

registrants to spend millions of dollars generating data.[36] This benefit is conferred merely because the follow-on companies wish neither to generate the data nor to purchase a registered active ingredient from a developer at a price that includes an element of cost recovery for the developer.

This benefit is clearly a private benefit that accrues only to these follow-on registrants. It is inconsistent with FIFRA's primary objective and, as shown above, results in little or no benefit to competition. *See* pp. 13-16, *supra*.

In the context of a health and safety statute, the suggestion that avoiding additional or "duplicative" testing somehow serves a public purpose strains credulity. There is no such thing as duplicative scientific testing. Additional testing is an important means of advancing scientific understanding, particularly since no two manufacturers use identical processes or produce identical chemicals. Contrary to the assertions in its brief, EPA has long recognized this fundamental principle:

> In toxicity testing, . . . the issue often is not merely whether a pesticide causes a particular toxic effect or how toxic the pesticide is, but also *how certain* we are of the validity of a set of findings. If a second test of a pesticide for some toxic effect produces results which corroborate the findings of an earlier test, each set of test results gains credibility from the other. On the other hand, if the second test results are significantly different (as is not uncommon in some kinds of toxicity testing), careful review is required to attempt to explain the differences and to decide what the Agency's position should be. Thus, the more data of a given type there are for comparison, the more con-

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[36] Attempts to legitimize mandatory licensing by characterizing it as a plan to remove "unnecessary" barriers to market entry and "needless" testing, App. Br. at 12, 17, 24; PPA Br. at 12, are simply wrong. Plainly, Congress has determined that those "barriers," the data submission requirements, are necessary to protect health, safety, and the environment. The question, therefore, is whether a few companies should escape the burden of satisfying those requirements.

> fident the Agency can be that its regulatory decision is sound.

44 Fed. Reg. 27945, 27946 (1979) (emphasis original).[37] Indeed, the benefits of additional tests in preventing the problems identified by *amici* supporting EPA—failure to disclose or discover adverse effects, difficulty in interpreting controversial data, and fraudulent test results[38]—would be substantial.[39] Thus, nothing could be farther from the truth than to suggest that the avoidance of additional testing serves a public purpose.[40]

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[37] *See also* EPA's P.R. Notice 83-4 (as amended by P.R. Notice 83-4A) (1983) setting forth the interim registration procedures being followed pending this Court's decision. Those procedures require each applicant either to generate and submit all required data on its own or to obtain a previous registrant's full, advance consent to the applicant's reliance on that registrant's data. EPA notes repeatedly that if an applicant has met this requirement, the Agency may review other data in its files before determining whether the pesticide may be registered. *Id.* at 5, 6, 9, 20. To limit this review to one set of data, even a complete one, "would not be a scientifically sound approach to evaluating whether a pesticidally active ingredient would cause unreasonable adverse effects." *Id.* at 9. EPA's policy would make no sense if repeated tests of the same substance would yield only "duplicative" results. *Amici* do not dispute EPA's contention that the Agency should be allowed to refer to all available data, once the applicant whose product is under review has either generated all the necessary data on its own or has obtained the permission of a data submitter to rely on the latter's data.

[38] *See* AFL-CIO Br. at 6 n.6; AAAS Br. at 4, 11-18.

[39] The PPA Brief's unsupported assertions that "[t]here is no jeopardy to public health and safety" as a result of the absence of data from follow-on registrants, and that generation of such data would be "unproductive," PPA Br. at 19-20, are therefore plainly wrong.

[40] It is equally illusory to suggest that mandatory licensing is necessary to serve the "public purpose" of preserving scarce testing resources. There is no reason to suppose that testing services would not grow to meet increased demand.

This case is not one where a statute serves public purposes and only "incidentally and gratuitously" confers private benefits, and is therefore constitutional. *Thompson* v. *Consolidated Gas Utilities Corp.*, 300 U.S. at 77. The mandatory licensing provisions are exactly the reverse: they serve private purposes with only incidental, if any, benefit to the public. They are therefore unconstitutional.

C. Even If The Taking Were For Public Purposes, It Would Be Unconstitutional Because Data Submitters Do Not Receive Just Compensation.

Even if the Court were to find that the mandatory licensing provisions serve public purposes, they would still be unconstitutional because of the unavailability of just compensation.

FIFRA fails completely to provide for just compensation to data developers. As a threshold matter, the statute's severe limitations on judicial review of arbitration decisions ignore the cardinal principle that the determination of adequate compensation is a judicial function. *Baltimore & Ohio Railroad* v. *United States*, 298 U.S. 349, 364-69 (1936); *United States* v. *New River Collieries Co.*, 262 U.S. 341, 343-44 (1923); *Monongahela Navigation Co.* v. *United States*, 148 U.S. 312, 327 (1893).

The provisions requiring follow-on registrants to offer to compensate developers for the use of their data do not result in just compensation,[41] even leaving aside the question whether any compensation from a private party can satisfy the government's obligation to compensate those from whom it takes

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[41] Neither of the other so-called "replacement rights" conferred on developers by FIFRA, App. Br. at 36, provides anything approaching just compensation. The ten-year exclusive use provision in FIFRA, applicable only to new active ingredients, does no more than return to the data submitter part of what the statute takes away. The argument that developers may, in turn, rely on other developers' data is no more than an attempt to justify one constitutional violation by the commission of another.

property. FIFRA contains no standards that assure that compensation will be a "full and perfect equivalent for the property taken," compensating the owner not only for the property taken but also for the revenues that would have been generated by the property. *Monongahela Navigation Co.* v. *United States*, 148 U.S. at 326-29, 343; *United States* v. *New River Collieries Co.*, 262 U.S. at 343. The three compensation decisions that have been issued to date have fallen far short of meeting that constitutional requirement.[42]

All three decisions have considered as compensable only the costs of performing tests rather than the value of the data generated. This approach undervalues the property taken. Developers' great investment in discovering and registering new products and uses, which is many times the cost solely of generating required registration data, suggests how much the value of being able to market a product can exceed the cost of the testing. Since all three decisions rejected the fair market value approach,[43] the compensation awarded was not "just" within the meaning of the Fifth Amendment.[44]

Furthermore, even under the cases' approach of considering costs rather than value, some costs have been deemed noncompensable. Unrecoverable costs include costs for data sub-

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[42] Stauffer Chemical Co. v. PPG Industries, Inc., Docket No. PPG Industries, Inc. 16-199-077-82 FIFRA (1983) (Birch, Smolka, and Vassil, Arb.) ("Stauffer"); Union Carbide v. Thompson-Hayward Chemical Co., FIFRA Comp. Docket No. 27 (1982) ("Thompson-Hayward"); Ciba-Geigy Corp. v. Farmland Industries, Inc., FIFRA Comp. Docket Nos. 33, 34, and 41 (1980) ("Farmland").

[43] Stauffer, slip op. at 17-18; Thompson-Hayward, slip op. at 67-69; Farmland, slip op. at 28-32.

[44] The value of the test data in question might be more fairly estimated on the basis of the entire effort resulting in the discovery and registration of the pesticide. However, this approach also has been rejected by the three cases. Stauffer, slip op. at 17; Thompson-Hayward, slip op. at 50-51; Farmland, slip op. at 44-45.

mitted before 1970 and not cited later;[45] efficacy studies performed to meet the statutory requirement that a product satisfy its label claims,[46] but not submitted;[47] efficacy studies required to be submitted by the initial registrant, if submission is no longer required at the time of the follow-on registration;[48] and safety data determined to be "substantially duplicative of other submitted data,"[49] even though such tests provide additional information, and may have been performed with the reasonable belief that the data were required to ensure registration.

Another fundamental shortcoming of the decisions has been their reliance on predicted market shares, which are inherently speculative. No procedure exists for modifying an award if market shares change substantially, as they well may, given the cost advantages enjoyed by the follow-on registrants.

In light of this uneven distribution of the costs of becoming a pesticide registrant, it is clear that mandatory licensing is not merely a regulation designed to adjust "the benefits and burdens of economic life," *Usery* v. *Turner Elkhorn Mining Co.*, 428 U.S. 1, 15 (1976). Rather, Congress has selected one segment of the pesticide industry to discharge, for the entire industry, the burdens of satisfying the health and safety concerns associated with the marketing and use of pesticides, and another small segment of the industry to escape sharing in those burdens. This is precisely the type of provision that is addressed by the constitutional limitations on takings of pri-

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[45] Such costs are not compensable under FIFRA § 3(c)(1)(D), 7 U.S.C. § 136a(c)(1)(D). Stauffer, slip op. at 6-7, 18.

[46] *See* Proposed Data Requirements, 47 Fed. Reg. 53192, 53197, 53214 (1982) (to be codified as 40 C.F.R. Part 158).

[47] EPA requires the actual submission of efficacy data only for products intended to control organisms posing human health threats. *See* 40 C.F.R. § 162.163(b)(2), 48 Fed. Reg. 34000, 34006 (1983).

[48] Stauffer, slip op. at 9-10.

[49] *Id.* at 18-19.

vate property: "The Fifth Amendment's guarantee . . . [is] designed to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne as a whole." *Armstrong* v. *United States*, 364 U.S. 40, 49 (1960). *See also Monongahela Navigation Co.* v. *United States*, 148 U.S. at 325.[50]

The district court's decision that mandatory licensing is unconstitutional is correct and should be affirmed.

III. THE COURT NEED NOT DECIDE AT THIS TIME WHETHER A DECISION IN FAVOR OF APPELLEE MUST BE RETROACTIVELY APPLIED, AND SHOULD NOT FORECLOSE RETROACTIVE APPLICATION IN APPROPRIATE CASES.

The PPA Brief suggests that a possible consequence of affirmance of the district court's decision would be the invalidation of existing follow-on registrations. PPA Br. at 5, 14. That brief thus implicitly invites the Court to address the question whether a decision in Monsanto's favor must be applied to registrations issued prior to that decision. The Court should reject the invitation to go beyond the record in this case, which raises only the question of prospective application, until it has before it a case and a record providing a basis for the factual inquiries relevant to a decision on retroactivity.

Based on the rule that a court must apply the law in effect at the time it decides a case even if the law has changed since the case first arose, *see United States* v. *The Schooner Peggy*, 5 U.S. (1 Cranch) 103 (1801), courts have traditionally presumed that a judicial decision will be applied to pending and subsequent cases involving events prior to the decision,[51] unless

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[50] *Amici* agree with Monsanto that the Tucker Act is not available to provide compensation for the taking of developers' data.

[51] *See, e.g.*, Gulf Offshore Co. v. Mobil Oil Corp., 453 U.S. 473, 486 n.16 (1981); Thorpe v. Housing Authority, 393 U.S. 268, 281-82 (1969); Johnson v. Lehman, 679 F.2d 918, 920-21 (D.C. Cir. 1982); Mullins v. Andrus, 664 F.2d 297, 302-03 (D.C. Cir. 1980).

such retroactivity would create "manifest injustice."[52] The leading decision on the analysis required to set aside the retroactivity presumption in a civil case is *Chevron Oil Co.* v. *Huson*, 404 U.S. 97 (1971). Under *Chevron*, a determination whether to limit a decision to prospective effect requires analysis of three questions:

(1) whether the decision establishes a new principle of law, either by overruling clear precedent on which litigants had relied, or by deciding an issue of first impression, the resolution of which was "not clearly foreshadowed";

(2) whether retroactive application would further or retard the purpose of the decision; and

(3) whether retroactivity would be inequitable.

Id. at 106-07.[53]

Because these three factors require careful analysis before the Court can properly foreclose retroactive relief, and because the record in this case does not provide the basis for such an analysis, this Court should refrain from addressing the question of retroactivity. Registrations issued prior to the district court's decision were approved under a wide variety of

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[52] As applied to decisions, such as that sought here, that a statute is unconstitutional, the general rule is reflected in this Court's comment that "[a]n unconstitutional act is not a law; it confers no rights; it imposes no duties; it affords no protection; it creates no office; it is, in legal contemplation, as inoperative as though it had never been passed." Norton v. Shelby County, 118 U.S. 425, 442 (1886).

[53] "[A]ll questions of civil retroactivity continue to be governed by the standard enunciated in Chevron Oil Co. v. Huson. . . ." United States v. Johnson, 457 U.S. 537, 563 (1982). Although *Chevron* involved a question of statutory interpretation, the opinion did not limit the test to such cases, and it has been applied to constitutional decisions. *See, e.g.*, Zweibon v. Mitchell, 606 F.2d 1172 (D.C. Cir. 1979), *cert. denied*, 453 U.S. 912 (1981); Dasho v. Susquehanna Corp., 461 F.2d 11 (7th Cir.), *cert. denied*, 408 U.S. 925 (1972).

factual circumstances. Retroactivity may not be appropriate for all of these registrations, but may be justified for some.

If the Court defers consideration of retroactivity, any review of existing registrations would presumably occur only after full administrative or judicial consideration. For example, FIFRA and EPA regulations provide that a registrant must be given notice of the Agency's intent to cancel and an opportunity for a full administrative hearing.[54] Such a hearing, or an action in court, would create a record providing a full basis for review of the appropriate extent of retroactive application. For instance, the record to be generated in the proceeding on Griffin's chlorothalonil registration[55] will reflect, *inter alia*, the effect of EPA's breach of a written agreement requiring advance notice of the use of SDS's data on behalf of another company, data compensation disputes still pending between SDS and Griffin at the time of the district court's decision, and the fact that there is not yet any Griffin chlorothalonil on the market.

Because of the wide variety of circumstances that may exist with respect to registrations issued before the decision in this case, this Court should decline to foreclose retroactive relief.

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[54] FIFRA § 6(b) and (d), 7 U.S.C. § 136d(b) and (d); 40 C.F.R. Part 164 (1983).

[55] *See* p. 2, *supra*.

CONCLUSION

The judgment of the district court should be affirmed.

Respectfully submitted,

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